DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

March 9, 2001

WARNING LETTER
CHI-20-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Elizabeth A. Savant, President
Savant Medical Supply, Inc.
1215 S. Harlem Avenue
Forest Park, IL 60130

Dear Ms. Savant:

During a January 30 through February 5, 2001, inspection of your oxygen transfilling facility, our investigator documented significant deviations of the current Good Manufacturing Practice for Finished Pharmaceuticals (CGMPs), Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act. The deviations observed during our inspection include, but are not limited to, the following:

Failure to test each batch of Liquid Oxygen, U.S.P. (LOX), for identity or purity prior to release for distribution. For example, your firm does not perform any tests on incoming bulk LOX before gas packs are transfilled from the bulk tank. The gas packs are then used to transfill cryogenic home vessels. The inspection also revealed your firm does not obtain Certificates of Analysis for bulk liquid oxygen. [21 CFR 211.165(a)]

Failure to establish adequate batch production and control records for each batch of drug product including documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished at the time of performance. For example, the inspection revealed that your firm does not document the filling of large cryogenic vessels (gas packs) from the standing tank. Also, there is no documentation of the prefill inspection on gas packs or cryogenic home vessels. [21 CFR 211.188(b)]

Failure to establish written procedures to assure that LOX has the identity and purity it purports or is represented by labeling to possess. The inspection revealed that your firm has no written procedures that address the transfilling of LOX. [21 CFR 211.100(a)]

Failure to properly calibrate the [redacted] Analyzer that is used to assay the Oxygen U.S.P. for purity and identity. The inspection revealed that your firm has not performed any filter changes required by the instruction manual. [21 CFR 211.160(b)(4)]

Failure to have written procedures that describe the handling of all written and oral complaints of possible failure of a drug product include a provision for review of the complaint by the quality control unit. In addition, the complaint files reviewed during the inspection did not contain a discussion of the results of the investigations or give a description of the nature of the complaint. [21 CFR 211.198(a) & (b)(1)]

Failure to describe the responsibilities and procedures applicable to the quality control unit in a written document. The document given to the investigator during the inspection only discussed the role of the Vice President of Operations in the supervision and training of employees involved in transfilling LOX. There was no discussion in this document of the approval or rejection of incoming bulk LOX, SOPs, label controls and the review or production records. [21 CFR 211.22(a)]

This letter, and the Form FDA 483, List of Observations (copy enclosed), issued to Matthew Kincaid, Vice President of Operations, at the conclusion of the inspection are not intended to be an all-inclusive list of violations found at your firm. It is your responsibility to ensure adherence with all requirements of the Act and that all applicable regulations are being met. Failure to achieve prompt corrections may result in regulatory action without further notice. This may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts.

Please notify this office in writing, within 15 working days, of the specific steps you have taken to correct the noted deviations and to prevent a recurrence of similar violations. Your response should be directed to George F. Bailey, Compliance Officer, at the above address.

Sincerely,

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Raymond V. Mlecko
District Director